

REMARKS/ARGUMENTS

Claims 48-98, and 101-127 are pending in this application. Claims 99 and 100 have been canceled. Claims 69, 86-97, 101-119, and 125 have been withdrawn from consideration and claims 48, 98, 101, 105, 108, 116, 118, 119, 122, 123, 124 and 127 have been amended.

Claim Rejections- 35 U.S.C. § 101

The Examiner rejected claims 99 and 100 under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. Claims 99 and 100 have been canceled.

Claim Rejections- 35 U.S.C. § 112

(i) Pluripotent Cells

The Examiner rejected claims 48-68, 70-85, 98-100, 120-124, 126 and 127 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement because the specification fails to provide teachings or guidance to show that the resulting hybrid cells are, indeed, pluripotent. Claims 99 and 100 have been canceled and independent claims 48, 123, 124 and 127 have been amended to read “hybrid” cells rather than “pluripotent” cells.

(ii) Recipient Cells

The Examiner has also rejected claims 48-68, 70-85, 98-100, 120-124, 126 and 127 under 35 U.S.C. § 112, first paragraph on the basis that the claims are overbroad since the claims encompass methods of nuclear transfer utilizing any mammalian oocyte. The Examiner cites to Campbell et al. (Cloning & Stem Cells, 3(4):201-208 (2001)) and Fulka et al. (Theriogenology, 55(6):1373-1380 (2001)) to conclude that the state of the art supports that only oocytes in MII or oocytes in telophase II be used for successful nuclear transfer. Applicants note that the pending claims recite methods of generating a hybrid mammalian cell by preparing more than one cytoplasmic fragment from a mammalian oocyte or fertilized zygote. Applicants also note that the claimed invention does not rely on any special type of oocyte.

The Examiner correctly states that presently at least three types of oocytes are available to those of skill in the art, as described by Fulka et al. In fact, other types of oocytes can be used, see for example, Miyoshi et al. (BMC Developmental Biology (2001) 1:12), which teaches the use of metaphase I stage oocytes and Baguisi et al. (Nature Biotech (1999) 17:456), which teaches the use of telophase II stage oocytes for nuclear transfer. Additionally, other types of oocytes may be discovered in the future. The specification teaches nuclear transfer to a cytoplasmic fragment of an oocyte or zygote. The type of oocyte is not relevant. Any oocyte that can be used for nuclear transfer, which is known to one skilled in the art of cloning, can be used. As the Examiner correctly notes, the specification does provide for the use of a metaphase II oocyte, thus the Applicants burden to provide at least one way to carry out the method of the present invention is fulfilled.

(iii) Activation

The Examiner has also rejected claims 48-68, 70-85, 98-100, 120-124, 126 and 127 rejected under 35 U.S.C. § 112, first paragraph for failure to provide a step of activating the resulting NT unit. Independent claims 48, 123, 124 and 127 have been amended to include an activation step: “(d) if an oocyte is used in step (a), then activating the oocyte before, during or after step (c).”

(iv) Human cloning

The Examiner has also rejected claims 48-68, 70-85, 98-100, 120-124, 126 and 127 rejected under 35 U.S.C. § 112, first paragraph because the breadth of the claimed invention encompasses the cloning of human cells. The Examiner contends that these embodiments are not enabling because of the art recognized inability to clone primates. With respect, we draw the Examiner's attention to the fact that none of the claims are directed to cloning animals. The claims clearly recite methods for producing hybrid mammalian cells. Therefore, we ask that the Examiner withdraw this rejection.

Claim Rejections- 35 U.S.C. § 102

Applicants thank the Examiner for withdrawing the prior rejections of claims 48, 54-67, 70-79, 81, 82, 84, 85, 98 as anticipated under 35 U.S.C. § 102(b) by WO 97/07668, Campbell et al., Wolf et al., Susko-Parrish et al. and Robl et al., which were cited in the previous Office Action. The Examiner maintained the rejection of claims 99 and 100 over these prior art references. Applicants have canceled claims 99 and 100, but reserve the right to prosecute these claims in a continuation application.

The Examiner has maintained the prior rejection of claims 47-57, 60-64, 66, 67, 70-74, 77, 78, 81, 82 and 98, 123, 124, 127 under 35 U.S.C. 102(b) as being anticipated by Peura (WO 98/29532). The Examiner notes: "Peura's methods are directed to producing reconstituted embryos, and they particularly teach a method of, '[I]ncreasing cytoplasmic volume in an embryonic cell said method including providing at least two cytoplasts prepared by a method of enucleating an oocyte, providing an embryonic cell; and fusing said cytoplasts with the embryonic cell.' Thus, Peura teaches the production of more than one enucleated cytoplasts as a means to fuse at least two whole, enucleated cytoplasts, not the production of smaller, cytoplasm fragments, as required by the pending claims. The claims thereby inherently require a decrease the total amount of cytoplasm contributed by the cytoplasm.

Further, the claims of a patent application are read in light of the teachings of the specification. The specification clearly teaches that the enucleated cytoplasm fragments are fractions of an oocyte, which constitute less than the entire cytoplasm, and that "smaller volume of cytoplasts will produce fewer problems of mitochondrial incompatibility (see, for example, paragraph [0067] of the specification).

It is respectfully believed that this application is in condition for allowance. Early action is respectfully requested. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Other than the petition fee, no additional fees are believed to be due in connection with this response. However, should the Commissioner determine otherwise, he is authorized to charge such fees and credit any overpayment to Deposit Account No. 11-0980.

Respectfully submitted,

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